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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/787,342	03/16/2001	Jan G. Tonnies	1497.4	7932
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22497 7590 06/09/2003

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EXAMINER

THISSELL, JEREMY

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/09/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,342

Applicant(s)

TONNIES, JAN G.

Examiner

Jeremy T. Thissell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102 or 103

Claim 6 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Langley et al (US 5,421,812).

Langley teaches a method for controlling the infusion of a therapeutic agent, using a microcontroller (col. 3, line 1), based on the half-life of the agent (col. 3, line 9) as a factor in determining the total amount of agent remaining in the patient (col. 3, lines 13-14). One reason cited for monitoring and controlling the amount of agent is to ensure the safety of the patient (col. 6, line 41). Since the device is automatically controlled with a microcontroller, it is inherent that the amount of agent in the body is compared to a predetermined safety threshold, above (or below) which the patient is in danger of overdose (and/or as is also the case in Langley, who infuses anticoagulant during blood transfusions, underdose, which is also dangerous in that case).

If Applicant does not agree that these limitations are inherently met by the disclosure of Langley, then the Examiner takes the position that these limitations would have been obvious to one of ordinary skill in the art as a well-known safety system of automatic infusion machines.

Claim Rejections - 35 USC § 103

Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zacouto (US 5,305,745) in view of Langley et al (US 5,421,812).

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Zacouto teaches an implantable pump device having an external remote control means (col. 15, lines 50-56). Zacouto teaches determination of frequency of monitoring measurements based on the half-life of the agent being infused. Zacouto also teaches that the measurements can be intermittent or continuous. However, Zacouto does not teach that the calculations of the amount of agent in the body are made based on the half-life of the agent.

Langley teaches calculation of the amount of agent based on the half-life. It would have been obvious to one of ordinary skill in the art, to utilize such calculation for the device of Zacouto, even as a secondary means of determining how much agent is in the body of the patient. Even though actual measurement as in Zacouto would be more accurate, the calculation would be a "safer" quantity to fall back on, in the event that the measuring means malfunctioned and took an accurate measurement. For example, if the measuring means somehow mistakenly registered a reading much lower than the actual amount in the body, then the infusion system would continue to add agent to the patient, which could actually push the level of agent in the patient over the safety threshold. However, the calculation of what "should" be left in the patient, after a particular time period, would at least give a rough estimate, which although it might not be as accurate, is much more reliable, than a measuring device.

Further, since the measurements can be taken intermittently, the computer may assume (without further notice, such as from the measurement) that the patient needs a predetermined amount of the agent, as is well-known in the art.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

This action is being made NON-FINAL in view of new grounds of rejection.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt

June 2, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700